Charles M. Lizza
William C. Baton
Sarah A. Sullivan
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiff
Jazz Pharmaceuticals Ireland Limited

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS IRELAND LIMITED, **Plaintiff,** **v.** **LUPIN LTD., LUPIN INC., and LUPIN PHARMACEUTICALS, INC.,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Jazz Pharmaceuticals Ireland Limited ("Jazz Pharmaceuticals"), by its undersigned attorneys, for its Complaint against Defendants Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. (together, "Lupin" or "Defendants"), alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq*., arising from Lupin's submission of Abbreviated New Drug Application ("ANDA") No. 215911 ("Lupin's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to manufacture, use, import, distribute, offer to sell, and/or sell a generic version of Jazz Pharmaceuticals's Xywav® drug products prior to the

expiration of United States Patent Nos. 8,591,922 ("the '922 patent"), 8,772,306 ("the '306 patent"), 8,901,173 ("the '173 patent"), 9,050,302 ("the '302 patent"), 9,132,107 ("the '107 patent"), 9,486,426 ("the '426 patent"), 10,195,168 ("the '168 patent"), 10,213,400 ("the '400 patent"), 10,675,258 ("the '258 patent"), and 10,864,181 ("the '181 patent") (collectively, "the patents-in-suit"), all owned by Jazz Pharmaceuticals.

The Parties

2. Plaintiff Jazz Pharmaceuticals Ireland Limited is a corporation organized and existing under the laws of Ireland, having a principal place of business at Waterloo Exchange, Waterloo Road, Dublin, Ireland 4.

3. On information and belief, Defendant Lupin Ltd. is a corporation organized and existing under the laws of India, having a place of business at B/4 Laxmi Towers, Bandra Kurla Complex Bandra (E), Mumbai, 400 051, India, and its registered office at Kalpataru Inspire 3rd Floor, Off Western Express Highway Santacruz (East), Mumbai 400 055, India.

4. On information and belief, Defendant Lupin Inc. is a corporation organized and existing under the laws of the State of Delaware, having places of business at 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202 and 400 Campus Drive, Somerset, New Jersey 08873.

5. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having places of business at 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202 and 400 Campus Drive, Somerset, New Jersey 08873.

6. On information and belief, Lupin Inc. and Lupin Pharmaceuticals, Inc. are wholly owned subsidiaries of Lupin Ltd.

The Patents-in-Suit

7. On November 26, 2013, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '922 patent, entitled, "Gamma-hydroxybutyrate compositions and their use for the treatment of disorders," to Jazz Pharmaceuticals as assignee. A copy of the '922 patent is attached hereto as Exhibit A.

8. On July 8, 2014, the USPTO duly and lawfully issued the '306 patent, entitled, "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters," to Jazz Pharmaceuticals as assignee. A copy of the '306 patent is attached hereto as Exhibit B.

9. On December 2, 2014, the USPTO duly and lawfully issued the '173 patent, entitled, "Gamma-hydroxybutyrate compositions and their use for the treatment of disorders," to Jazz Pharmaceuticals as assignee. A copy of the '173 patent is attached hereto as Exhibit C.

10. On June 9, 2015, the USPTO duly and lawfully issued the '302 patent, entitled, "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters," to Jazz Pharmaceuticals as assignee. A copy of the '302 patent is attached hereto as Exhibit D.

11. On September 15, 2015, the USPTO duly and lawfully issued the '107 patent, entitled, "Gamma-hydroxybutyrate compositions and their use for the treatment of disorders," to Jazz Pharmaceuticals as assignee. A copy of the '107 patent is attached hereto as Exhibit E.

12. On November 8, 2016, the USPTO duly and lawfully issued the '426 patent, entitled, "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters," to Jazz Pharmaceuticals as assignee. A copy of the '426 patent is attached hereto as Exhibit F.

13. On February 5, 2019, the USPTO duly and lawfully issued the '168 patent, entitled, "Gamma-hydroxybutyrate compositions and their uses for the treatment of disorders," to Jazz Pharmaceuticals as assignee. A copy of the '168 patent is attached hereto as Exhibit G.

14. On February 26, 2019, the USPTO duly and lawfully issued the '400 patent, entitled, "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters," to Jazz Pharmaceuticals as assignee. A copy of the '400 patent is attached hereto as Exhibit H.

15. On June 9, 2020, the USPTO duly and lawfully issued the '258 patent, entitled, "Method of using gamma-hydroxybutyrate compositions for the treatment of disorders," to Jazz Pharmaceuticals as assignee. A copy of the '258 patent is attached hereto as Exhibit I.

16. On December 15, 2020, the USPTO duly and lawfully issued the '181 patent, entitled, "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters," to Jazz Pharmaceuticals as assignee. A copy of the '181 patent is attached hereto as Exhibit J.

The Xywav® Drug Product

17. Jazz Pharmaceuticals holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for calcium, magnesium, potassium, and sodium oxybates oral solution (NDA No. 212690), which it sells under the trade name Xywav®. The claims of the patents-in-suit cover, *inter alia*, methods of use and administration of calcium, magnesium, potassium, and sodium oxybates, or pharmaceutical compositions containing calcium, magnesium, potassium, and sodium oxybates.

18. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Xywav®.

19. The labeling for Xywav® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Xywav® for the treatment of cataplexy or excessive daytime sleepiness in patients with narcolepsy .

20. The labeling for Xywav® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to modify the dose of Xywav® for patients receiving calcium, magnesium, potassium, and sodium oxybates when divalproex sodium (valproate) is concomitantly administered.

21. The labeling for Xywav® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Xywav® according to one or more of the methods claimed in the patents-in-suit.

Acts Giving Rise To This Suit

22. Pursuant to Section 505 of the FFDCA, Lupin submitted Lupin's ANDA seeking approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of 0.5 g/mL calcium, magnesium, potassium, and sodium oxybates oral solution ("Lupin's Proposed Product") before the patents-in-suit expire.

23. On information and belief, following FDA approval of Lupin's ANDA, Lupin will make, use, sell, or offer to sell Lupin's Proposed Product throughout the United States, or import such generic products into the United States.

24. On information and belief, in connection with the submission of Lupin's ANDA as described above, Lupin provided written certifications to the FDA pursuant to Section 505 of

the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Lupin's Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Lupin's ANDA.

25. No earlier than June 16, 2021, Lupin sent a written notice of its Paragraph IV Certification to Jazz Pharmaceuticals ("Lupin's Notice Letter"). Lupin's Notice Letter alleged that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Lupin's ANDA. Lupin's Notice Letter also informed Jazz Pharmaceuticals that Lupin seeks approval to market Lupin's Proposed Product before the patents-in-suit expire.

Jurisdiction and Venue

26. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

27. On information and belief, Lupin Ltd. derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

28. This Court has personal jurisdiction over Lupin Ltd. because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in the State of New Jersey, including directly or indirectly through its subsidiaries, agents, and/or alter egos, Lupin Inc. and Lupin Pharmaceuticals, Inc., companies with a regular and established place of business in New Jersey; and (2) maintains extensive and systematic contacts with the State of New Jersey, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Lupin Inc. and Lupin Pharmaceuticals, Inc.

29. On information and belief, Lupin Inc. derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

30. This Court has personal jurisdiction over Lupin Inc. because, *inter alia*, it: (1) on information and belief, maintains a regular and established, physical place of business at 400 Campus Drive, Somerset, New Jersey 08873; (2) has purposefully availed itself of the privilege of doing business in the State of New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, Lupin Pharmaceuticals, Inc., a company with a regular and established place of business in New Jersey; and (3) maintains extensive and systematic contacts with the State of New Jersey, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Lupin Pharmaceuticals, Inc. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Lupin Inc. On information and belief, Lupin Inc. purposefully has conducted and continues to conduct business in this Judicial District.

31. This Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Lupin Pharmaceuticals, Inc. maintains a regular and established, physical place of business at 400 Campus Drive, Somerset, New Jersey 08873. On information and belief, Lupin Pharmaceuticals, Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0101043376. On information and belief, Lupin Pharmaceuticals, Inc. is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No.

5005159. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. On information and belief, Lupin Pharmaceuticals, Inc. purposefully has conducted and continues to conduct business in this Judicial District.

32. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. are in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. also prepare and/or aid in the preparation and submission of ANDAs to the FDA, including Lupin's ANDA.

33. On information and belief, this Judicial District is a likely destination for the generic drug products described in Lupin's ANDA.

34. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. derive substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

35. This Court also has personal jurisdiction over Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. because, *inter alia*, they have committed an act of patent infringement under 35 U.S.C. § 271(e)(2). On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. intend a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Jazz Pharmaceuticals in New Jersey and in this Judicial District.

36. In the alternative, this Court has personal jurisdiction over Lupin Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Jazz Pharmaceuticals's

claims arise under federal law; (b) Lupin Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Lupin Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Lupin Ltd. satisfies due process.

37. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. work in privity and/or concert either directly or indirectly through one or more of their wholly owned subsidiaries with respect to the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

38. On information and belief, each of Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. actively participated in the submission of Lupin's ANDA. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will work in privity and/or concert with one another and/or other related entities towards the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including Lupin's Proposed Product, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the patents-in-suit.

39. On information and belief, Lupin Ltd. intends to benefit directly if Lupin's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of Lupin's ANDA.

40. On information and belief, Lupin Inc. intends to benefit directly if Lupin's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of Lupin's ANDA.

41. On information and belief, Lupin Pharmaceuticals, Inc. intends to benefit directly if Lupin's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of Lupin's ANDA.

42. On information and belief, Lupin Inc. and Lupin Pharmaceuticals, Inc. act at the direction, and for the benefit, of Lupin Ltd. and are controlled and/or dominated by Lupin Ltd.

43. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. act, operate, and/or hold themselves out to the public as a single integrated business.

44. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. have previously been sued in this District and have not challenged personal jurisdiction. *See, e.g., AstraZeneca AB, et al. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 3:09-cv-05404 (JAP)(TJB) (D.N.J.); *Abbott Labs and Laboratories Fournier S.A. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 2:09- cv-01007 (GEB)(MCA) (D.N.J.); *Abbott Labs and Laboratories Fournier S.A. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 2:10-cv-01578 (DMC)(JAD) (D.N.J.); *Tibotec Inc. and Tibotec Pharm. v. Lupin Ltd., et al.*, Civ. Action No. 2:10-cv-05954 (WHW)(MAS) (D.N.J.); *Novartis Corp., et al. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 2:06-cv-05954 (GEB)(ES) (D.N.J.); *Elan Int'l. Ltd. and Fournier Laboratories Ireland Ltd. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 2:09-cv-01008 (GEB)(MCA) (D.N.J.), *Jazz Pharmaceuticals, Inc., et al. v. Lupin Ltd., et al.*, Civ. Action No. 2:15-cv-06548 (ES)(JAD) (D.N.J.), *Horizon Pharma Ireland Limited, et al. v. Lupin Ltd., et al.*, Civ. Action No. 1:15-cv-06935 (NLH)(AMD) (D.N.J.), *Senju Pharmaceutical Co., Ltd, et al. v.*

Lupin Ltd., et al., Civ. Action No. 1:16-cv-01097 (JBS)(KMW) (D.N.J.), *Bausch Health Ireland Ltd., et al. v. Lupin Ltd., et al.*, 1:20-cv-11039 (RMB)(KMW) (D.N.J.), *Merck Sharp & Dohme BV, et al. v. Lupin Ltd., et al.*, 2:20-cv-02786 (CCC)(MF) (D.N.J.), and *Bristol-Myers Squibb Co. v. Lupin Ltd., et al.*, 3:20-cv-07810 (MAS)(TJB) (D.N.J.).

45. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and/or 1400(b).

Count I: Infringement of the '922 Patent

46. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

47. Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.'s submission of their ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Lupin's Proposed Product, prior to the expiration of the '922 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

48. There is a justiciable controversy between the parties hereto as to the infringement of the '922 patent.

49. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will infringe one or more claims of the '922 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States.

50. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will induce infringement of one or more claims of the '922 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or

importing Lupin's Proposed Product in or for the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will intentionally encourage acts of direct infringement with knowledge of the '922 patent and knowledge that their acts are encouraging infringement.

51. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will contributorily infringe one or more claims of the '922 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. have had and continue to have knowledge that Lupin's Proposed Product is especially adapted for a use that infringes one or more claims of the '922 patent and that there is no substantial non-infringing use for Lupin's Proposed Product.

52. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.'s infringement of the '922 patent is not enjoined.

53. Jazz Pharmaceuticals does not have an adequate remedy at law.

54. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '306 Patent

55. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

56. Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.'s submission of their ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale

in, or importation into, the United States of Lupin's Proposed Product, prior to the expiration of the '306 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

57. There is a justiciable controversy between the parties hereto as to the infringement of the '306 patent.

58. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will infringe one or more claims of the '306 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States.

59. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will induce infringement of one or more claims of the '306 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will intentionally encourage acts of direct infringement with knowledge of the '306 patent and knowledge that their acts are encouraging infringement.

60. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will contributorily infringe one or more claims of the '306 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. have had and continue to have knowledge that Lupin's Proposed Product is especially adapted for a use that infringes one or

more claims of the '306 patent and that there is no substantial non-infringing use for Lupin's Proposed Product.

61. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.'s infringement of the '306 patent is not enjoined.

62. Jazz Pharmaceuticals does not have an adequate remedy at law.

63. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count III: Infringement of the '173 Patent

64. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

65. Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.'s submission of their ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Lupin's Proposed Product, prior to the expiration of the '173 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

66. There is a justiciable controversy between the parties hereto as to the infringement of the '173 patent.

67. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will infringe one or more claims of the '173 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States.

68. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will induce infringement of one or more claims of the '173 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will intentionally encourage acts of direct infringement with knowledge of the '173 patent and knowledge that their acts are encouraging infringement.

69. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will contributorily infringe one or more claims of the '173 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. have had and continue to have knowledge that Lupin's Proposed Product is especially adapted for a use that infringes one or more claims of the '173 patent and that there is no substantial non-infringing use for Lupin's Proposed Product.

70. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.'s infringement of the '173 patent is not enjoined.

71. Jazz Pharmaceuticals does not have an adequate remedy at law.

72. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV: Infringement of the '302 Patent

73. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

74. Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.'s submission of their ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Lupin's Proposed Product, prior to the expiration of the '302 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

75. There is a justiciable controversy between the parties hereto as to the infringement of the '302 patent.

76. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will infringe one or more claims of the '302 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States.

77. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will induce infringement of one or more claims of the '302 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will intentionally encourage acts of direct infringement with knowledge of the '302 patent and knowledge that their acts are encouraging infringement.

78. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will contributorily infringe one or more claims of

the ’302 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Lupin’s Proposed Product in or for the United States. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. have had and continue to have knowledge that Lupin’s Proposed Product is especially adapted for a use that infringes one or more claims of the ’302 patent and that there is no substantial non-infringing use for Lupin’s Proposed Product.

79. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.’s infringement of the ’302 patent is not enjoined.

80. Jazz Pharmaceuticals does not have an adequate remedy at law.

81. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

Count V: Infringement of the ’107 Patent

82. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

83. Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.’s submission of their ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Lupin’s Proposed Product, prior to the expiration of the ’107 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

84. There is a justiciable controversy between the parties hereto as to the infringement of the ’107 patent.

85. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will infringe one or more claims of the '107 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States.

86. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will induce infringement of one or more claims of the '107 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will intentionally encourage acts of direct infringement with knowledge of the '107 patent and knowledge that their acts are encouraging infringement.

87. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will contributorily infringe one or more claims of the '107 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. have had and continue to have knowledge that Lupin's Proposed Product is especially adapted for a use that infringes one or more claims of the '107 patent and that there is no substantial non-infringing use for Lupin's Proposed Product.

88. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.'s infringement of the '107 patent is not enjoined.

89. Jazz Pharmaceuticals does not have an adequate remedy at law.

90. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VI: Infringement of the '426 Patent

91. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

92. Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.'s submission of their ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Lupin's Proposed Product, prior to the expiration of the '426 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

93. There is a justiciable controversy between the parties hereto as to the infringement of the '426 patent.

94. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will infringe one or more claims of the '426 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States.

95. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will induce infringement of one or more claims of the '426 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will intentionally encourage acts of direct infringement with knowledge of the '426 patent and knowledge that their acts are encouraging infringement.

96. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will contributorily infringe one or more claims of the '426 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. have had and continue to have knowledge that Lupin's Proposed Product is especially adapted for a use that infringes one or more claims of the '426 patent and that there is no substantial non-infringing use for Lupin's Proposed Product.

97. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.'s infringement of the '426 patent is not enjoined.

98. Jazz Pharmaceuticals does not have an adequate remedy at law.

99. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VII: Infringement of the '168 Patent

100. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

101. Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.'s submission of their ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Lupin's Proposed Product, prior to the expiration of the '168 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

102. There is a justiciable controversy between the parties hereto as to the infringement of the '168 patent.

103. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will infringe one or more claims of the '168 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States.

104. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will induce infringement of one or more claims of the '168 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will intentionally encourage acts of direct infringement with knowledge of the '168 patent and knowledge that their acts are encouraging infringement.

105. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will contributorily infringe one or more claims of the '168 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. have had and continue to have knowledge that Lupin's Proposed Product is especially adapted for a use that infringes one or more claims of the '168 patent and that there is no substantial non-infringing use for Lupin's Proposed Product.

106. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.'s infringement of the '168 patent is not enjoined.

107. Jazz Pharmaceuticals does not have an adequate remedy at law.

108. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VIII: Infringement of the '400 Patent

109. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

110. Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.'s submission of their ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Lupin's Proposed Product, prior to the expiration of the '400 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

111. There is a justiciable controversy between the parties hereto as to the infringement of the '400 patent.

112. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will infringe one or more claims of the '400 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States.

113. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will induce infringement of one or more claims of the '400 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or

importing Lupin's Proposed Product in or for the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will intentionally encourage acts of direct infringement with knowledge of the '400 patent and knowledge that their acts are encouraging infringement.

114. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will contributorily infringe one or more claims of the '400 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. have had and continue to have knowledge that Lupin's Proposed Product is especially adapted for a use that infringes one or more claims of the '400 patent and that there is no substantial non-infringing use for Lupin's Proposed Product.

115. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.'s infringement of the '400 patent is not enjoined.

116. Jazz Pharmaceuticals does not have an adequate remedy at law.

117. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IX: Infringement of the '258 Patent

118. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

119. Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.'s submission of their ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale

in, or importation into, the United States of Lupin's Proposed Product, prior to the expiration of the '258 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

120. There is a justiciable controversy between the parties hereto as to the infringement of the '258 patent.

121. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will infringe one or more claims of the '258 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States.

122. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will induce infringement of one or more claims of the '258 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will intentionally encourage acts of direct infringement with knowledge of the '258 patent and knowledge that their acts are encouraging infringement.

123. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will contributorily infringe one or more claims of the '258 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. have had and continue to have knowledge that Lupin's Proposed Product is especially adapted for a use that infringes one or

more claims of the ’258 patent and that there is no substantial non-infringing use for Lupin’s Proposed Product.

124. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.’s infringement of the ’258 patent is not enjoined.

125. Jazz Pharmaceuticals does not have an adequate remedy at law.

126. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

Count X: Infringement of the ’181 Patent

127. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

128. Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.’s submission of their ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Lupin’s Proposed Product, prior to the expiration of the ’181 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

129. There is a justiciable controversy between the parties hereto as to the infringement of the ’181 patent.

130. Unless enjoined by this Court, upon FDA approval of Lupin’s ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will infringe one or more claims of the ’181 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Lupin’s Proposed Product in or for the United States.

131. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will induce infringement of one or more claims of the '181 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will intentionally encourage acts of direct infringement with knowledge of the '181 patent and knowledge that their acts are encouraging infringement.

132. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will contributorily infringe one or more claims of the '181 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. have had and continue to have knowledge that Lupin's Proposed Product is especially adapted for a use that infringes one or more claims of the '181 patent and that there is no substantial non-infringing use for Lupin's Proposed Product.

133. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.'s infringement of the '181 patent is not enjoined.

134. Jazz Pharmaceuticals does not have an adequate remedy at law.

135. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Jazz Pharmaceuticals respectfully requests the following relief:

(A) A Judgment that Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. have infringed the patents-in-suit by submitting ANDA No. 215911;

(B) A Judgment that Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. have infringed, and that Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.'s making, using, selling, offering to sell, or importing Lupin's Proposed Product will infringe, one or more claims of the patents-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 215911 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Jazz Pharmaceuticals is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. and their officers, agents, attorneys, and employees, and those acting in privity and/or concert with them, from making, using, offering to sell, selling, or importing Lupin's Proposed Product until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Jazz Pharmaceuticals is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc., their officers, agents, attorneys, and employees, and those acting in privity and/or concert with them, from practicing any compositions or methods claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Jazz Pharmaceuticals is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, offer for sale, or sale in, and/or importation into, the United States of Lupin's Proposed Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc., their officers, agents, attorneys, and/or employees, or those acting in privity and/or concert with them, have committed any acts with respect to the compositions or methods claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Jazz Pharmaceuticals damages for such acts;

(H) If Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc., their officers, agents, attorneys, and/or employees, or those acting in privity and/or concert with them, engages in the commercial manufacture, use, offer for sale, or sale in, and/or importation into, the United States of Lupin's Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Jazz Pharmaceuticals resulting from such infringement, together with interest;

(I) A Judgment declaring that the patents-in-suit remain valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Jazz Pharmaceuticals its attorneys' fees incurred in this action;

(K) A Judgment awarding Jazz Pharmaceuticals its costs and expenses incurred in this action; and

(L) Such further and other relief as this Court may deem just and proper.

Dated: July 28, 2021

By: s/ Charles M. Lizza
Charles M. Lizza
William C. Baton
Sarah A. Sullivan
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiff
Jazz Pharmaceuticals Ireland Limited

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Andrew S. Chalson
Gabriel P. Brier
Frank C. Calvosa
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000

CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matter in controversy involves one of the same plaintiffs, some of the same patents (the '306 patent, the '302 patent, and the '426 patent), and the same defendants as the matters captioned *Jazz Pharmaceuticals, Inc., et al. v. Lupin Ltd., et al.*, C.A. No. 15-6548 (ES)(JAD) (D.N.J.) (complaint filed on September 1, 2015, civil case terminated on January 15, 2016) and *Jazz Pharmaceuticals, Inc., et al. v. Lupin Limited, et al.*, C.A. No. 18-8267 (ES)(JAD) (D.N.J.) (complaint filed on April 24, 2018, civil case terminated on May 14, 2018)—both of which were consolidated with *Jazz Pharmaceuticals, Inc., et al. v. Amneal Pharmaceuticals, LLC,* C.A. No. 13-391 (ES)(JAD) (D.N.J.).

I further certify that the matter in controversy involves one of the same plaintiffs and some of the same patents (the '306 patent, the '302 patent, and the '426 patent) that were at issue in the matters captioned *Jazz Pharmaceuticals, Inc., et al. v. Amneal Pharmaceuticals, LLC*, C.A. No. 15-1043 (ES)(JAD) (D.N.J.) (complaint filed on February 2015, civil case terminated on April 21, 2015); *Jazz Pharmaceuticals, Inc., et al. v. Amneal Pharmaceuticals, LLC*, C.A. No. 15-6562 (ES)(JAD) (D.N.J.) (complaint filed on September 2, 2015, civil case terminated on April 25, 2016); and *Jazz Pharmaceuticals, Inc., et al. v. Amneal Pharmaceuticals LLC*, C.A. No. 17-1440 (ES)(JAD) (D.N.J.) (complaint filed on March 1, 2017, civil case terminated on May 14, 2018)—all of which were consolidated with *Jazz Pharmaceuticals, Inc., et al. v. Amneal Pharmaceuticals, LLC,* C.A. No. 13-391 (ES)(JAD) (D.N.J.).

I further certify that the matter in controversy involves one of the same plaintiffs and some of the same patents (the '306 patent and the '302 patent) that were at issue in the matters captioned *Jazz Pharmaceuticals, Inc., et al. v. Par Pharmaceutical, Inc.*, C.A. No. 14-6150

(ES)(JAD) (D.N.J.) (complaint filed on October 2, 2014, civil case terminated on April 21, 2015); *Jazz Pharmaceuticals, Inc., et al. v. Ranbaxy Laboratories Limited, et al.*, C.A. No. 14-6151 (ES)(JAD) (D.N.J.) (complaint filed on October 2, 2014, civil case terminated on April 21, 2015); *Jazz Pharmaceuticals, Inc., et al. v. Watson Laboratories, Inc.*, C.A. No. 14-7757 (ES)(JAD) (D.N.J.) (complaint filed on December 11, 2014, civil case terminated on April 22, 2015); *Jazz Pharmaceuticals, Inc., et al. v. Wockhardt Bio AG, et al.*, C.A. No. 15-5619 (ES)(JAD) (D.N.J.) (complaint filed on July 17, 2015, civil case terminated on January 15, 2016); *Jazz Pharmaceuticals, Inc., et al. v. Par Pharmaceutical, Inc.*, C.A. No. 15-7580 (ES)(JAD) (D.N.J.) (complaint filed on October 19, 2015, civil case terminated on August 15, 2017); *Jazz Pharmaceuticals, Inc., et al. v. Sun Pharmaceutical Industries Ltd., et al.*, C.A. No. 15-8229 (ES)(JAD) (D.N.J.) (complaint filed on November 23, 2015, civil case terminated on April 26, 2016); and *Jazz Pharmaceuticals, Inc., et al. v. Watson Laboratories, Inc.*, C.A. No. 16-1505 (ES)(JAD) (D.N.J.) (complaint filed on March 17, 2016, civil case terminated on June 28, 2016)—all of which were consolidated with *Jazz Pharmaceuticals, Inc., et al. v. Amneal Pharmaceuticals, LLC,* C.A. No. 13-391 (ES)(JAD) (D.N.J.).

I further certify that the matter in controversy involves one of the same plaintiffs and some of the same patents (the ’306 patent and the ’302 patent) as the consolidated matters captioned *Jazz Pharmaceuticals, Inc., et al. v. Roxane Laboratories, Inc.*, C.A. No. 15-1360 (ES)(JAD) (D.N.J.) (complaint filed on February 20, 2015, civil case terminated on April 11, 2017) and *Jazz Pharmaceuticals, Inc., et al. v. Roxane Laboratories, Inc.*, C.A. No. 16-469 (ES)(JAD) (D.N.J.) (complaint filed on January 27, 2016, civil case terminated on March 29, 2016). I further certify that the matter in controversy involves one of the same plaintiffs and one of the same patents (the ’302 patent) as the matter captioned *Jazz Pharmaceuticals, Inc., et al. v.*

Wockhardt Bio AG, et al., C.A. No. 16-99 (ES)(JAD) (D.N.J.) (complaint filed on January 7, 2016, civil case terminated on April 26, 2016). I further certify that the matter in controversy involves one of the same plaintiffs and some of the same patents (the '306 patent, the '302 patent, and the '426 patent) as the matters captioned *Jazz Pharmaceuticals, Inc., et al. v. Ascent Pharmaceuticals, Inc.*, C.A. No. 17-5487 (ES)(JAD) (D.N.J.) (complaint filed on July 27, 2017, civil case terminated on August 29, 2017) and *Jazz Pharmaceuticals, Inc., et al. v. Mallinckrodt plc, et al.*, C.A. No. 18-29 (ES)(JAD) (D.N.J.) (complaint filed on January 2, 2018, civil case terminated on June 15, 2018).

To the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: July 28, 2021

By: s/ Charles M. Lizza

Charles M. Lizza
William C. Baton
Sarah A. Sullivan
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiff
Jazz Pharmaceuticals Ireland Limited

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Andrew S. Chalson
Gabriel P. Brier
Frank C. Calvosa
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000